



January 27, 2022

BY ELECTRONIC SUBMISSION

U.S. Department of Health and Human Services
Centers for Medicare & Medicaid Services
Department of Health & Human Services
P.O. Box 8016
Baltimore, MD 21244-8016

Re: Request for Public Comment Concerning Proposed Rule on Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, File Code CMS-9911-P, RIN 0938-AU65

Dear Secretary Xavier Becerra:

On behalf of The Christian Medical & Dental Associations® (CMDA), we respectfully submit the following comments on the proposed rule, published in 87 Fed. Reg. 584 (Jan. 5, 2022), in the above-captioned matter. We write to express our concern with the proposed Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2023, RIN 0938-AU55.

The Christian Medical & Dental Associations® (CMDA) was founded in 1931 and provides programs and services supporting its mission to "change hearts in healthcare" with a current membership of around 19,000 healthcare professionals. CMDA promotes positions and addresses policies on healthcare issues; conducts overseas medical education and evangelism projects; coordinates a network of Christian healthcare professionals for fellowship and professional growth.

Standards of care for individuals who identify as transgender are still being debated within the medical community-particularly as those standards apply to children and permanently life altering interventions.²

² See, e.g., Azeen Ghorayshi, Doctors Debate Whether Trans Teens Need Therapy Before Hormones, NYT (Jan. 13, 2022), <https://www.nytimes.com/2022/01/13/health/transgender-teens-hormones.html>.

An area of concern is the influence of the World Professional Association for Transgender Health (WPATH). Several sources cite that this organization is more of an activist group rather than an entity based in science and fact. WPATH provides "guidelines" that are in the least questionable and at the most harmful. Please see the following:

The current World Professional Association for Transgender Health (WPATH) "standards of care" (SOC 7)¹ (discussed in more detail below) are a case in point. They lack an evidentiary research base, are the

¹ World Professional Assn for Transgender Health, Standards of Care Version 7 (2018), <https://www.wpath.org/publications/soc>.

product of a membership body that includes non-professionals and activists and reflect an ideological bias. In fact, the WPATH “standards of care” are self-described as “flexible guidelines” (or suggestions) and clinicians practicing in the area of “transgender medicine” widely disregard the supposed standards they set. For example, a recent research article noted that the assessment criteria followed by Mount Sinai medical center diverged from the WPATH guidelines in the vast majority of cases.² A 2022 meta-analysis of “gender affirming” surgeries describing the WPATH guidelines, notes their weak evidentiary basis: “Although World Professional Association for Transgender Health policies set guideline recommendations for clinical decision-making, the evidence base remains widely scattered, with no reviews that unify gender surgery across all facets.”³ Yet, the preamble to the proposed rule positively cites WPATH as a “professional society” that has “published criteria for guidelines in treating gender dysphoria and gender-affirming care for transgender people.” 87 Fed. Reg. at 667.

WPATH is an advocacy group and not a scientific organization.

“Instead of being a scientifically based organization, WPATH acts as a politically active entity pushing aggressively for worldwide acceptance of gender incongruence as a biologically-based variation of normal behavior. WPATH pushed the American Psychiatric Association to eliminate GID as a disorder. Dr. Zucker, who chaired the committee to create the DSM-5, fought to retain an entity, which he termed Gender Dysphoria, to describe the emotional suffering of those persons with gender incongruence. This would allow patients to receive insurance coverage for treatments related to resolving the dysphoria. He succeeded in his efforts and the term GID was thus replaced.”

Quentin L. Van Meter. Bringing Transparency to the Treatment of Transgender Persons. *Issues in Law & Medicine*, Vol. 34, Iss. 2, Fall 2019, pp. 147-152.

Contradictory. “The **World Professional Association for Transgender Health’s Standards of Care recommend an informed consent process, which is at odds with its recommendation of providing hormones on demand.**”

Stephen B. Levine (2018): Informed Consent for Transgendered Patients, *Journal of Sex & Marital Therapy*, DOI: 10.1080/0092623X.2018.1518885

The World Professional Association for Transgender Health (WPATH) deems gender identity incongruity not “inherently pathological” and asserts that efforts to “change gender identity and expression to become more congruent” with biological sex ineffective [ignores evidence, see below] and “unethical.”

Coleman E, Bockting W, Botzer M, et al. Standards of Care for the Health of Transsexual, Transgender, and Gender-Nonconforming People, Version 7. *International Journal of Transgenderism* 2012; **13**(4): 165-232.

(WPATH’s citation for the alleged lack of success of psychotherapy fail to support their claim. At least 15 studies or case reports exist. Michelle Cretella, Transgender Belief: A Call to Heal Minds, Preserve Bodies, and Save Lives, Joint AAPLOG/ACPeds Matthew Bulfin Medical Education Conference (online: 2020).)

² **CITATION Mount Sinai study**

³ Oles N, Darrach H, Landford W, Garza M, Twose C, Park CS, Tran P, Schechter LS, Lau B, Coon D. Gender Affirming Surgery: A Comprehensive, Systematic Review of All Peer-reviewed Literature and Methods of Assessing Patient-centered Outcomes (Part 1: Breast/Chest, Face, and Voice). *Ann Surg*. 2022 Jan 1;275(1):e52-e66. doi: 10.1097/SLA.0000000000004728. PMID: 33443903.

“This makes AAP’s logic entirely backwards: That WPATH’s request to depathologize gender dysphoria was rejected suggests that it is WPATH’s view—and therefore the AAP policy—which fall “outside the mainstream of traditional medical practice.” (!)”

James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, Journal of Sex & Marital Therapy, DOI:10.1080/0092623X.2019.1698481

AAP’s HealthDay reported (April 2017) U of Iowa study that kids younger than 14yo could not reliably cross a busy street safely.

- <https://consumer.healthday.com/kids-health-information-23/child-safety-news-587/at-what-age-can-kids-safely-cross-the-street-721785.html>.
- So how can they be competent to choose GAT?

“But the American Academy of Pediatrics is now on record prioritizing the opinion of a five-year-old over the considered judgment of the child’s parents.”

“The AAP would not allow a five-year-old to veto the parent’s decision regarding whether to be vaccinated against diphtheria, which is today a very rare disease. Why is the AAP giving five-year-olds supreme authority for this much more profound decision?”

“These new guidelines are not based in evidence. On the contrary, they contradict the available research.”

Leonard Sax, “Politicizing Pediatrics: How the AAP’s Transgender Guidelines Undermine Trust in Medical Authority,”thepublicdiscourse.com March 13, 2019.

<https://www.thepublicdiscourse.com/2019/03/50118/>

CMDA is concerned with the physiological harm that Gender Assignment Therapy may cause. This is clearly evidenced in the following points:

Summary of Problems with Gender (Transition) Affirming Care, Hormones, and Surgeries.

- Gender [transition] affirming therapy is not the standard of care.
- The international standard of care is “watchful waiting,” including extensive psychological support and evaluation of the child and family both. ^{i ii iii iv v}
- UK High Court Bell v Tavistock Dec. 12, 2020 ruling that GAT/TAT in minors was experimental, not proven safe or effective, and required court order for those under 16 and that court order was advisable for those 16-17. ^{vi}
- NHS issued amendments to Gender Identity Development Service specifications for minors Dec 2020 to comply with Bell v Tavistock. ^{vii}
- Transgenderism as the catch-all explanation for distress, & transition is promoted as a cure-all solution. ^{viii}
- Skilled psychological investigation for underlying causes is shamed as “transphobic”. ^{ix}
 - Those underlying causes and contributors – which are always there – don’t vanish with GAT, they are the seeds of regret, and they must be dealt with.
- **The chemical sterilization/castration and surgical mutilation of normal sex organs in children is not healthcare.**

PUBERTY BLOCKING AGENTS

- There is international questioning of GAT/TAT for minors occurring on national levels in UK (Bell v Tavistock, NHS GIDS protocol amendments),^x Sweden (Karolinska hospital no longer issuing hormones to minors under 16)^{xi}, Finland,^{xii} Australia,^{xiii} Brazil, etc.
- Puberty blocking agents (PBA) given at Tanner stage II likely causes infertility and we don't know if it really is reversible.^{xiv xv}
 - Puberty blockers can also cause problems by inducing early menopause in females.
- PBA use in precocious puberty and prostate cancer treat diseases where benefits outweigh risks.
 - PBA use in GD kids causes disease (hypogonadotropic hypogonadism) in otherwise healthy kids.^{xvi}
 - Not FDA approved for this.
 - Puberty is not a disease state but a normal stage of life.
- Following PBA's with cross-sex hormones (CSH) assures sterility.
PBAs and CSH will interrupt the vital pubertal window for development of
- brain, bones and psychology. No one can have that window back.
- The myth of PBAs as "pause buttons" that "buy time" to "wait and see."
 - PBA are Gateway drugs, select persistence rather than natural desistance. Commits a child to CSH and SRS/GAS.
 - 5 studies show PBA use results in persistence 96.5-100%.
 - Laidlaw, et al: "In a study of 70 adolescents who were followed **after receiving PBA, 100% desired to continue on to cross-sex hormones** (de Vries et al. 2011). The natural pattern of desistance has been broken..."^{xvii}
 - The **discontinuation rate** for transition **after initiating PB is low**. 1.4% per Wiepjes, et al.,^{xviii} 1.9% per Brik, et al.,^{xix} and 3.5% per Kuper, et al.^{xx}, and 2% per Carmichael, et al.^{xxi}
- **PBA Risk Summary.**
 - Not fully reversible, long-term complications possible even if PBAs stopped early^{xxii}
 - Infertility risk (blocks development of sperm and ova)
 - Genitalia arrested in underdeveloped stage
 - Sexual dysfunction
 - Males: erectile, orgasmic and ejaculatory impairment
 - Females: menopausal state inducing
 - Mental health issues: mood swings, depression, suicidal ideation and attempts (Lupron package insert).^{xxiii xxiv}
 - Bone mineral density compromise at its period of greatest growth. Osteopenia/-porosis?^{xxv}
 - Hindering of brain development milestones
 - Loss of puberty time frame to self and with peers

POTENTIAL HARMS ASSOCIATED WITH CROSS SEX HORMONE THERAPY:

- **With CSH: a biological female body experiences male levels of testosterone, something never seen outside of an androgen-secreting tumor. It's a iatrogenic pathological state.**
 - "The Endocrine Society's guidelines recommend elevating females' testosterone levels from a normal of 10 to 50 ng/dL to 300 to 1000 ng/dL, values typically found with androgen secreting tumors."^{xxvi}
- **COMPLICATIONS OF CSH THERAPY:**^{xxvii xxviii xxix}
 - Cross Sex Hormones (CSH)
 - Testosterone
 - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
 - Breast/uterine cancer
 - Liver dysfunction
 - HTN
 - Severe acne
 - Liver cancer?^{xxx}
 - Estrogen
 - Dyslipidemias
 - Thromboembolic disease (blood clots)
 - Cardiovascular and cerebrovascular disease (heart attacks and strokes)
 - Breast cancer^{xxxi}
 - Weight gain
 - Insulin resistance
 - Cholelithiasis
 - **Testosterone increases the risk of heart disease in women 4 fold, Estrogen increases the rate of deep vein thrombosis (blood clots) and stroke in men 3 to 5 fold, heart attacks 2 fold.**^{xxxii xxxiii xxxiv xxxv}
 - **The increased risk of venous thromboembolism (VTE) in biological males taking estrogen increased further with duration of use from four-times greater after two years to over sixteen-times greater after eight years of use compared to males not using estrogen.**^{xxxvi}
 - In a 2019 nationwide cohort study of the Netherlands, of 1129 trans women (natal males) who were taking estrogen, **the incidence of breast cancer "was 46-fold higher than in cisgender men"**.^{xxxvii}
 - **Estrogen (in MtF) can cause increased weight gain^{xxxviii} and insulin resistance.**^{xxxix}

Sex reassignment surgery (SRS)/gender affirming surgery (GAS)/gender confirming surgery (tops, bottoms, contouring, etc.):

- Is cosmetic, creating poorly functioning pseudo-genitalia.
 - Usually no orgasms.
 - Sterility is guaranteed by absence of ovaries and testicles.
- Rated by the Hayes Directory with the lowest possible rating for strength of evidence. The Centers for Medicare & Medicaid did not issue a National Coverage Determination for it due to poor proof.
- 2011 Swedish study (Dhejne) of all their SRS patients over 30 years (324) showed 19 times the completed suicide rate 10 years out. ^{xi}
- 2019 (online) Bränström and Pachankis. First total population study of 9.7 million Swedish residents. ^{xli} Ultimately showed neither “gender-affirming hormone treatment” nor “gender-affirming surgery” provided reductions of the mental health treatment benchmarks examined. ^{xlii}

In conclusion, there is concern about the effects this proposed rule could have particularly on children’s long-term physical and mental health. HHS itself has had reservations about the efficacy and outcomes of “gender reassignment surgery.” During the Obama administration, the Department declined to issue a national coverage mandate for such surgery in its own programs. Center for Medicare & Medicaid Services, Decision Memo for Gender Dysphoria and Gender Reassignment Surgery, CAG-00446N (Aug. 30, 2016) (finding that “the clinical evidence is inconclusive,” that “there is not enough high quality evidence to determine whether gender reassignment surgery improves health outcomes,” and that “we cannot exclude therapeutic interventions as a cause of the observed excess morbidity and mortality”). So in agreement with previous HHS reservations, CMDA urges you to not move forward with this current proposed rule.

Respectfully Submitted,
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Christian Medical & Dental Associations
Washington D.C Office

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ⁱⁱ Michael Laidlaw, Michelle Cretella & Kevin Donovan (2019) The Right to Best Care for Children Does Not Include the Right to Medical Transition, *The American Journal of Bioethics*, 19:2, 75-77, DOI: [10.1080/15265161.2018.1557288](https://doi.org/10.1080/15265161.2018.1557288)

ⁱⁱⁱ James M. Cantor (2019): Transgender and Gender Diverse Children and Adolescents: Fact-Checking of AAP Policy, *Journal of Sex & Marital Therapy*, DOI:10.1080/0092623X.2019.1698481

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- ^v de Vries, A. L., and P. T. Cohen-Kettenis. 2012. Clinical management of gender dysphoria in children and adolescents: The Dutch approach. *Journal of Homosexuality* 59(3): 301–320.
- ^{vi} <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>
- ^{vii} <https://www.england.nhs.uk/wp-content/uploads/2020/12/Amendment-to-Gender-Identity-Development-Service-Specification-for-Children-and-Adolescents.pdf>
- ^{viii} Littman, L. “Rapid-onset gender dysphoria in adolescents and young adults: A study of parental reports,” *journals.plos.org*, Aug. 16, 2018. <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0202330>.
- ^{ix} “NHS 'over-diagnosing' children having transgender treatment, former staff warn,” *news.sky.com*, 12 Dec. 2019. <https://news.sky.com/story/nhs-over-diagnosing-children-having-transgender-treatment-former-staff-warn-11875624>
- ^x <https://www.judiciary.uk/wp-content/uploads/2020/12/Bell-v-Tavistock-Judgment.pdf>
- ^{xi} [Karolinska Policyförändring K2021-3343 March 2021 \(Swedish\).pdf](#); [Karolinska Policy Change K2021-3343 March 2021 \(English, unofficial translation\).pdf](#)
- ^{xii} https://palveluvalikoima.fi/documents/1237350/22895008/Summary_minors_en.pdf/aaf9a6e7-b970-9de9-165c-abadfae46f2e/Summary_minors_en.pdf
- ^{xiii} https://www.binary.org.au/australians_demand_inquiry_into_child_puberty_blockers.
- ^{xiv} Michael K. Laidlaw, Quentin L. Van Meter, Paul W. Hruz, Andre Van Mol, and William J. Malone, Letter to the Editor: Endocrine Treatment of Gender-Dysphoria/Gender-Incongruent Persons: An Endocrine Society* Clinical Practice Guideline, *JCEM*, Online, November 23, 2018.
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